Next slide.

Daniel Lessler, M.D.: Robert, can I ask you a quick question about the definition of ER mention?

Roger Chow: Yeah.

Daniel Lessler, M.D.: How does that...what...how do they decide what constitutes being mentioned? I mean, is it-…

Roger Chow: Yeah, it's a little bit vague, actually. The people are trained at these ERs. And so any time there's an intake, I believe, they have someone who's trained to kind of ascertain whether they think the ER visit is significantly related to an opioid. So I think there's some subjectivity there. But it also...I think they also incorporate urine tox-screens and things like that. So, there's a...they used to have a criteria to determine the link. But...and of course they train people at the different centers. That's probably as much as I can tell you about it. The DAWN study...there's a whole web site just devoted to the DAWN study where they have kind of pages and pages of data. And I actually am not sure how detailed they go into in terms of their message. But we can actually look into that some more, if that would be of interest.

Daniel Lessler, M.D.: Thank you.

Roger Chow: So the next line on other observational studies...so yesterday, actually, there was just an article in The Oregonian...it was either yesterday or the day before, where the State of Oregon has reported the number of deaths that occurred last year, and the numbers are either 96 or 104 depending on which method was used. So I think the health examiner reported a slightly lower number and then somebody who did some other type of analysis reported a slightly higher number. So it doesn't look like it's increased in 2002 at least, but it's still concerning because [Inaudible] deaths [Inaudible] with Methadone are high. I mean, they've increased since back in '99. Again, the increase since 1999 appears to be related to an increase in prescription, but, of course, there is a concern that, you know, Methadone has a potential because of its irregular half life and maybe provider inexperience, that if the [Inaudible] is broken that there is a potential for problem if people are converted to Methadone. So that's been a concern. And I think the message from yesterday's news report...I haven't seen that come out on the official Oregon website though, I'm sure it will pretty soon, is that at least the numbers of deaths haven't increased since 2002. I did see on the news report that they had done more [Inaudible] of the number of prescription. So my guess would be prescriptions since 2002 are about the same or have gone up. So, for what that's worth, we'll see what they have to say when they come out with their official report. There was also a case series of 96 Methadone associated deaths from 1992 to 2002 in kind of a [Inaudible] prescribing pattern. 15% were chronic pain patients. I think from all the...from both the State of Oregon and the Minnesota data what would be really helpful would be to see similar kinds of data on other long-acting opiates and try to figure out whether this increase in Methadone has [Inaudible] be seen with other long-acting opioids. And I haven't seen anything [Inaudible] yet.

Next slide. So this is long-acting vs. short-acting opioid safety. Again, the same seven trials that we've reported previously, no pattern suggesting that either long or short-acting opioids are safer.

Next slide. [Inaudible] populations. Really no new data to report on [Inaudible] populations. I [Inaudible] I should update this part of the bit. There's more data on neuropathic pain, but all the studies compare long-acting opiates to the placebo and don't really compare long-acting opiates to each other. So not able to tell whether one drug is superior or not to another for neuropathic pain. There continues to be almost no information on age, race or gender. People at high risk for [Inaudible] have generally been excluded from all of these trials.

Next slide. [Inaudible] what I just mentioned, a few trials that were excluded may be of interest. One was a head-to-head trial of Transdermal Fentanyl vs. long-acting Morphine that I mentioned at the beginning. As far as we can tell it's [Inaudible] but it sounds like, from the public comment we've received, that it has been accepted and we will continue to look for that. Again, this is by one of the same authors that previously did [Inaudible] I probably put it in the report. There are two short-term placebo controlled trials of Transdermal [Inaudible] Morphine, but this drug is not available in the U.S. so we have excluded it. [Inaudible] drug is undergoing the FDA approval process so we went to the FDA website, but we'll just need to keep an eye on that. We don't have [Inaudible] Hydromorphone yet. There's only published an abstract at this point and [Inaudible] cancer patient. We'll be keeping our eye out for that. [Inaudible] and Oxymorphone, of course, this drug is not yet approved. It's undergoing the approval process and so far all we have are abstracts for that.

So, next slide. So in summary, we still only have three head-to-head trials. None are good quality. We await [Inaudible] and hydromorphone. Currently the FDA approval is only at the 2nd line agent people already on moderate doses of opioids. Two of the new trials were drugs that we didn't have trials on before; Levorphanol and Methadone. Both of these use unusual designs and in addition to other problems with comparison; because they weren't directly compared to other opioids the design makes comparison even more difficult. [Inaudible] quality is generally poor. We do have those two large California Medicaid studies that suggest that constipation may be less with transdermal Fentanyl than with Oxycodone, but again concerns about significant base [Inaudible] differences between groups with virtually any demographic variable that you look at. There is no evidence that one long-acting opioid is superior to others or that long-acting opioids as a class are superior to short-acting. We can [Inaudible] the risk for Methadone but unable to really look at that in context with the other drugs, though there is certainly concern and [Inaudible] generally excluded from these trials as no one's done a good observational study looking at that risk.

I think that's it. Next slide. Yeah, that's it. So, I guess we have time for questions, if anybody has questions.

Daniel Lessler, M.D.: Thank you, Roger, for a good update. I was going to open it to committee members for questions on the update for Roger.

Roger Chow: Great.

Daniel Lessler, M.D.: It doesn't look like there are many questions. I think the essence of your comments, Roger, really would suggest that there isn't much in the way of meaningful new data out there from a clinical perspective at this point compared to the prior report.

Roger Chow: No, I don't think so. I think the...you know, I should probably comment a little bit more about the constipation issue with Fentanyl because it has been looked at in cancer patients and the findings of those two observational studies are consistent with what's been seen in cancer patients. So it could very well be a real finding. But, you know, because we're really focusing on the non cancer [Inaudible] population, this is all the data we have. So just to kind of maybe take that into consideration that this may be kind of an emerging data to really look at. And I think the other areas really with Methadone safety, I mean, really it's getting a lot of attention. And Oregon, specifically is getting a lot of attention and I think elsewhere in the country the question of safety of Methadone combined with kind of a continued lack of good study on Methadone, this continues to be an issue. We just wish there were better studies on some of these drugs. So I'll just leave it at that.

Daniel Lessler, M.D.: Thanks. Jeff?

Jeff Thompson, M.D.: [Inaudible] talk a little bit about this other DUR...this is Jeff Thompson, but we at Medicaid are also concerned with the safety and efficacy in this class. You may have been contacted. We just launched our product notification program where we're notifying...we've identified the top three [Inaudible] clients who need ten or more prescriptions of narcotics by multiple providers in any one month and are providing you, the providers, the information of who is making those prescriptions and whether they're getting those from emergency rooms. So we are very concerned about this and trying to work with providers to talk with each other because we do not have a good system to track these. And we'll continue to work in that fashion.

Roger Chow: I think one of the issues with Methadone, especially, is conversion. Then the question is almost...and I think there are two separate questions. One is whether Methadone is inherently more dangerous than other drugs, which I'm not sure we have data on that. The other question is whether it's more dangerous because providers are using it inappropriately because they're not converting it appropriately, which is more of, I think of, an education issue than that the drug itself is more dangerous. But it's really hard to sort those things out and I'm not sure if you can sort them out. But to me they seem to be kind of two separate issues. But if you can [Inaudible] providers are using the drugs appropriately, which is what we hope they are doing, you know, how safe are they...that's really the question we want to ask in an education component is maybe a separate thing. Yeah, it continues to be brought up, and like I said, it was, you know, front page in the Metro section in The Oregonian yesterday the Methadone death issue.

Daniel Lessler, M.D.: [Inaudible].

Carol Cordy, M.D.: I have a question, Jeff. Carol Cordy here. Are there any...do you have any data showing an increased use of Methadone preferred on the Preferred Drug List?

Jeff Thompson, M.D.: Well, I think you basically...back prior to November of '03 there was about 70% utilization of brand drugs. Once prior authorization of the Preferred Drug List came into effect that has gone down to 30%. So like I don't have the actual numbers, but the increase of preferred drugs, Methadone to long-acting morphine [Inaudible] has increased [Inaudible]. They are the preferred drugs. They are now 70% of the market share. They used to be 30% of the market share.

Carol Cordy, M.D.: And does Washington have numbers like Oregon?

Jeff Thompson, M.D.: We...there are published data, I mean, from DOH looking at a number of excess deaths relating at both illicit and non illicit drugs; Morphine, Methadone...I'm not clear about Fentanyl and some of the other ones, but I know the Department of Health a number of the officers are concerned about overdosing [Inaudible] drugs. And we are working with them and that is why at least starting with the top 300 working with positions. We're also included in that, those top 300 clients are being referred to the PRO program where they would be restricted to one physician, one hospital and one pharmacy. And then we're also working with GOTHA to refer those top 320 clients over for basically [Inaudible] consideration for money for drug treatment. So we're doing a lot. I think it's a very good balance of looking at the balance equation for looking at access to look at quality and we're tending to cost issues [Inaudible]. In my mind I think its working. I think there's a huge amount of education that needs to occur in data sharing at the provider level to take care of some of these other issues that are occurring with [Inaudible].

Carol Cordy, M.D.: And how was that number...ten seems awfully high.

Jeff Thompson, M.D.: There's some published data on where you do the cut point. Obviously the sensitivities best fit the issue. The further down you go...five or more you start getting into is it medically necessary, not medically necessary. There's published data on this that it was...we looked at the numbers and said this is something we could do in pilot. This is something that seems to be [Inaudible] abuse and misuse. After three months we'll come back to you and basically tell you what the results are. Actually if it's greater than ten prescriptions for schedule two, schedule three in any one month of last year or seven or more prescriptions in any six-month period or the two certain cut points. Not really good data to say, you know, where it is 100%. And I might include, though, this does not include oncology clients and this does not include hospice care. So this is non oncology, non hospice care.

Daniel Lessler, M.D.: Are there any other questions for Robert? Patty?

Patti Varley, ARNP: This is Patti Varley. A question. When we made this motion previously, which led to the changes from brand to more generic use, and I know there was at least some issue with conversion, do we have any data about the implementation of what we did in regard to safety data? In regard to death or injury from the motion we made before?

Roger Chow: Related to deaths we have not combined that database. It's something that we can look at [Inaudible]. I have not heard [Inaudible] from the providers around...I mean, that was a concern but it's really calmed down.

Patti Varley, ARNP: I know with Methadone we don't really encourage it as a preferred drug it's just drug if they feel comfortable using it or if they're familiar with it. I think we more...you know, we ask them to try long-acting morphine generic, but we don't really ask them to try Methadone unless it's their choice. We try to keep that to their discretion because of those issues that they don't know how to use it. We don't want them to try.

Roger Chow: And we also add it on the second round as one of the preferred drugs after we [Inaudible] preferred drugs, Methadone, long-acting Morphine or [Inaudible] currently the preferred agents. It is a concern. It's very difficult to actually tie cause and effect. We are working with coordinates. This is a big push for us so the more we get educated and we educate the provider community we're doing due diligent, probably not enough.

Man: What is the most used drug in that preferred category?

Nicole: It's the morphine. Yeah. I don't know...I wish I knew the numbers, but I think most of the increase has been in the morphine. But I can't tell you the exact number [Inaudible]. Like the generic [Inaudible]. I have a question for Dr. Chow

Roger Chow: Yes.

Nicole: This is Nicole with Washington Medicaid. I was just trying to remember if you...I don't know if you've seen this, it was Cathy Ketchum down at Oregon. I remember her doing a presentation on the Methadone test in Oregon State where they took out data. I don't know...have you seen this and am I remembering it correct? [Inaudible]…

Roger Chow: Yeah [Inaudible]…

Nicole: And there was no increase in Medicaid clients specifically?

Roger Chow: I kind of vaguely remember it. I think it was...I think what they did was they controlled for prescription use, but they kind of found the same thing that the state found overall, that numbers of deaths did go up but it was because...or it seemed related to the fact that you were doubling or tripling the number of people getting Methadone. But I believe the results were very similar from the results that the State reported as a whole.

Nicole: Thank you.

Daniel Lessler, M.D.: Where I see the biggest issue is the lack of connectivity between both prescribing versus what you prescribing. I mean, it's really very amazing for these [Inaudible] clients that we have identified with ten or more prescriptions that touch about 3,000 physicians.

Daniel Lessler, M.D.: [Inaudible].

Man: Questions for Robert? We do have one stakeholder signed up to speak here. Then...I just wonder if there's any effort that's being made to look at our Methadone overdose rates and whether they've changed at all. Sounds like in our state Methadone's just not used much. Probably...it's not going to be like Oregon where there's a real increase in usage in Methadone whereas we haven't. So it may be just a moot point as whether we should look at that. But is there an effort made to look at those deaths and the numbers and whether there's been any change?

Roger Chow: We'll report back to you in September if I can connect and work with Maxine [Inaudible] of Department of Health. We'll look at that. So far we haven't gotten the feedback, but we are working with the Department of Health. But I'll report back to you.

Daniel Lessler, M.D.: We do have one person signed up, Dr. Nancy Lewis.

Nancy Lewis: My name is Nancy Lewis. I am a pharmacist. I have experience...clinical experience in clinical care, oncology and pain management. I am currently employed as a medical liaison with Purdue Pharma, and today I am going to briefly discuss one of our products, Oxycontin, which is the [Inaudible] release. The need for today's discussion really is based upon current surveys indicating that as many as 50 million AmErikans are at least partially or completely disabled by persistent pain. [Inaudible] the cost of uncontrolled pain to [Inaudible] at a cost of $100 billion each year in health care utilization expenses, lost productivity, compensation and litigation. In a statement to the US Food and Drug Administration the Anesthetic and Life Support Drug Advisory Committee Dr. Richard Payne, who has been the president of the AmErikan [Inaudible] Society, noted that for many patients one drug does not fit all. Studies indicate that 80% of patients they require one switch of opiate medications and 20% of patients require three or more switches of medications to manage their pain in the most optimal manner. Even though opiates derive from the same general chemical family, there are important chemical differences in the ways in which patients respond to specific drugs. Therefore, it's essential to have many opioid medications and formulations available for clinicians to provide [Inaudible] clinical possibility that allow optimization of therapy and individualization of treatment of patients. In addition, the treating clinician needs to take differences in potency, side effect profiles, metabolites, [Inaudible] kinetic profiles and delivery systems into account based on the individual patient's situation. With this in mind, I'll now briefly discuss Oxycontin.

Oxycontin tablets are indicated for managing moderate to severe pain with continuous, around-the-clock analgesic [Inaudible] for an extended period of time. It is not indicated for p.r.n. use. The safety and efficacy of Oxycontin has been studied in moderate to severe pain due to various etiologies which include cancer, osteoarthritis, diabetic neuropathy and post-herpetic neuralgia. It provides analgesic within 1 hour in most patients and prolonged pain control [Inaudible] 12-hour dosing. So the most common side effects seen with Oxycontin include constipation, nausea, somnolence, dizziness, vomiting, [Inaudible], headache, dry mouth, sweating, and weakness. Severe adverse reactions are those observed with other opioid analgesics including respiratory depression, hypertension and shock. Oxycontin tablets are to be swallowed whole and are not to be broken, chewed or crushed. Purdue Pharma has designed a